

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ACADIA PHARMACEUTICALS INC.,

Plaintiff,

v.

HETERO LABS LIMITED,  
HETERO LABS LIMITED UNIT-V, and  
HETERO USA INC.,

Defendants.

C.A. No.: 20-01022-RGA

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**HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, AND  
HETERO USA INC.’S ANSWER TO ACADIA PHARMACEUTICAL  
INC.’S COMPLAINT**

Defendants Hetero Labs Limited (“Hetero Labs Ltd.”), Hetero Labs Limited Unit-V (“Hetero Labs Ltd. Unit-V”), and Hetero USA Inc. (“Hetero USA”) (collectively “Defendants” or “Hetero”), by and through their attorneys, answer the Complaint of Plaintiff Acadia Pharmaceuticals Inc. (“Plaintiff” or “Acadia”) and assert their affirmative defenses as follows. As used herein, “Defendants” or “Hetero” refers to and means the three named Hetero defendants collectively, namely, Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, and Hetero USA, Inc. Except as otherwise specifically stated in this Answer, Hetero denies each and every allegation of Plaintiffs’ Complaint.

**THE PARTIES**

1. Hetero is without information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 1 of the Complaint; therefore, denied.

2. Hetero admits Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India. Otherwise, denied

3. Hetero admits that Hetero Labs Ltd. Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabub Nagar, 509301, Andhra Pradesh, India. Otherwise, denied.

4. Hetero admits that Hetero USA is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 1035 Centennial Ave, Piscataway, New Jersey 08854.

5. Hetero admits Hetero Labs Ltd. Unit-V is a division of Hetero Labs Ltd. and that Hetero USA undertakes certain regulatory activities in the United States for Hetero Labs Ltd. Otherwise, denied.

6. Hetero admits that Hetero USA is a partially-owned subsidiary of Hetero Labs Ltd.

7. Hetero admits that Hetero USA is a partially-owned subsidiary of Hetero Labs Ltd. and that collectively those entities engage in activities related to the regulatory approval, manufacture, marketing, and/or sale of drug products. Otherwise, denied.

8. Hetero admits that Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, and Hetero USA Inc. are related entities and that the entities collectively undertake certain activities related to the regulatory approval, manufacture, marketing, and/or sale of drug products in the United States. Otherwise, denied.

9. Admitted that Hetero has prepared and filed Abbreviated New Drug Application (“ANDA”) No. 214828 for Pimavanserin Tartrate Capsules Eq 34 mg base (the “ANDA

Product”), and seeks FDA approval of the same. Paragraph 9 further contains allegations that concern future events that have not occurred and thus are not amenable to admission or denial; therefore, these allegations are denied. Hetero denies all remaining allegations of Paragraph 9.

#### **NATURE OF THE ACTION**

10. Hetero admits that this purports to be an action for patent infringement related to the referenced patents. Otherwise, denied.

#### **JURISDICTION AND VENUE**

11. Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero does not contest subject matter jurisdiction over Plaintiff’s claims for infringement under 35 U.S.C. § 271(e)(2)(A), but denies that the Court has jurisdiction over any claims for infringement under 35 U.S.C. § 271 (a), (b), and/or (c). Otherwise, denied.

12. Admitted.

13. Hetero does not contest venue for the purposes of this action only. Otherwise, denied.

14. Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction or venue for purposes of this action only. Otherwise, denied.

15. Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction for purposes of this action only. Otherwise, denied.

16. Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction or venue for purposes of this action only. Otherwise, denied.

17. Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero USA is incorporated in Delaware and Hetero does not contest venue for purposes of this action only. Otherwise, denied.

18. Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction or venue for purposes of this action only. Otherwise, denied.

19. Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero USA is incorporated in Delaware and Hetero does not contest personal jurisdiction or venue for purposes of this action only. Otherwise, denied.

20. Admitted.

21. Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction or venue for purposes of this action only. Otherwise, denied.

22. Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero does not contest venue for purposes of this action only. Otherwise, denied.

23. Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction or venue for purposes of this action only. Otherwise, denied.

24. Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction or venue for purposes of this action only. Otherwise, denied.

25. Denied.

26. Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction or venue for purposes of this action only. Otherwise, denied.

27. Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction for purposes of this action only. Otherwise, denied.

**ACADIA'S NDA AND THE PATENTS-IN-SUIT**

28. Hetero admits that the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the electronic “Orange Book,” identifies New Drug Application (“NDA”) No. 210793 for NUPLAZID® (Pimavanserin Tartrate) Capsule, Eq 34 mg base, and further identifies Acadia Pharmaceuticals Inc. as the holder of NDA 210793. Hetero is without sufficient information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 28; therefore, denied.

29. Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of U.S. Patent No. 7,601,740 (“the ’740 patent”) is entitled “Selective serotonin 2A/2C receptor inverse agonists as therapeutics for neurodegenerative diseases” and identifies an issue date of October 13, 2009. Hetero denies all remaining allegations of Paragraph 29.

30. Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '740 patent identifies Acadia Pharmaceuticals, Inc. as the assignee. Hetero denies all remaining allegations of Paragraph 30.

31. Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of U.S. Patent No. 10,449,185 (the "'185 patent") is entitled "Formulations of pimavanserin" and identifies an issue date of October 22, 2019. Hetero denies all remaining allegations of Paragraph 31.

32. Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '185 patent identifies Acadia Pharmaceuticals Inc. as the assignee. Hetero denies all remaining allegations of Paragraph 32.

33. Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of U.S. Patent No. 10,646,480 (the "'480 patent") is entitled "Formulations of pimavanserin" and identifies an issue date of May 12, 2020. Hetero denies all remaining allegations of Paragraph 33.

34. Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '480 patent identifies Acadia Pharmaceuticals Inc. as the assignee. Hetero denies all remaining allegations of Paragraph 34.

35. Hetero admits that the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book,"

identifies the '740, '185, and '480 patents as covering NUPLAZID® or its use. Otherwise, denied.

**HETERO'S ANDA AND PARAGRAPH IV NOTIFICATION**

36. Admitted that Hetero USA Inc. submitted ANDA No. 214828 to the FDA, and that ANDA No. 214828 seeks FDA approval to engage in the manufacture and sale of the ANDA product prior to the expiration of the patents-in-suit. Otherwise, denied.

37. Admitted that Hetero informed the FDA that its proposed ANDA product contains the same active ingredient as NUPLAZID®, and that Hetero also submitted proposed labeling for its proposed ANDA Product to the FDA. Otherwise denied.

38. Upon information and belief, admitted.

39. Admitted.

40. Paragraph 40 contains legal conclusions to which no answer is required.

41. Denied.

42. Admitted.

43. Admitted.

44. Admitted.

45. Denied.

**COUNT I—INFRINGEMENT BY HETERO LABS, HETERO UNIT-V,  
AND HETERO USA**

46. Hetero incorporates its answers to Paragraphs 1-45 as if fully set forth herein.

47. Denied.

48. Admitted.

49. Admitted. Hetero further answers that Hetero bore no obligation to identify all defenses in the Notice Letter, and Hetero expressly reserves the right to raise any additional

defenses related to invalidity, unenforceability, and non-infringement of one or more of the patents-in-suit in its Notice Letter.

50. Admitted. Hetero further answers that Hetero bore no obligation to identify all defenses in the Notice Letter, and Hetero expressly reserves the right to raise any additional defenses related to invalidity, unenforceability, and non-infringement of one or more of the patents-in-suit in its Notice Letter.

51. Paragraph 51 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Hetero USA prepared and filed ANDA No. 214828 and seeks FDA approval of the same. Hetero further admits that Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, and Hetero USA Inc. each undertook certain activities related to the development of ANDA No. 214828. Otherwise, denied.

52. Hetero admits that it was aware of the existence of the patents-in-suit at the time it filed ANDA No. 214828. Otherwise, denied.

53. Denied.

54. Paragraph 54 contains allegations concerning future events that have not occurred. For this and other reasons, Hetero denies the allegations of Paragraph 54.

55. Denied.

56. Denied.

#### **RESPONSE TO PLAINTIFF'S REQUEST FOR RELIEF**

Hetero denies that Plaintiff is entitled to the relief as requested in paragraph A-G of the Complaint's Request for Relief or to any relief whatsoever.



### **AFFIRMATIVE DEFENSES**

Without prejudice to the denials set forth in the Answer, without admitting any allegation in the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Hetero asserts the following affirmative defenses:

#### **FIRST AFFIRMATIVE DEFENSE**

*(Non-infringement of U.S. Patent No. 7,601,740)*

The manufacture, use, sale, offer for sale, or importation of the Pimavanserin Tartrate Capsules Eq 34 mg base that is the subject of ANDA No. 214828 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, directly or indirectly, any valid and enforceable claim of the patent-in-suit, either literally or under the doctrine of equivalents.

#### **SECOND AFFIRMATIVE DEFENSE**

*(Invalidity of U.S. Patent No. 7,601,740)*

The claims of the patent-in-suit are invalid and/or unenforceable for failure to comply with the requirements for patentability set forth in one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for double patenting.

#### **THIRD AFFIRMATIVE DEFENSE**

*(Non-infringement of U.S. Patent No. 10,449,185)*

The manufacture, use, sale, offer for sale, or importation of the Pimavanserin Tartrate Capsules Eq 34 mg base that is the subject of ANDA No. 214828 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, directly or indirectly, any valid and enforceable claim of the patent-in-suit, either literally or under the doctrine of equivalents.

**FOURTH AFFIRMATIVE DEFENSE**  
***(Invalidity of U.S. Patent No. 10,449,185)***

The claims of the patent-in-suit are invalid and/or unenforceable for failure to comply with the requirements for patentability set forth in one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for double patenting.

**FIFTH AFFIRMATIVE DEFENSE**  
***(Non-infringement of U.S. Patent No. 10,646,480)***

The manufacture, use, sale, offer for sale, or importation of the Pimavanserin Tartrate Capsules Eq 34 mg base that is the subject of ANDA No. 214828 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, directly or indirectly, any valid and enforceable claim of the patent-in-suit, either literally or under the doctrine of equivalents.

**SIXTH AFFIRMATIVE DEFENSE**  
***(Invalidity of U.S. Patent No. 10,646,480)***

The claims of the patent-in-suit are invalid and/or unenforceable for failure to comply with the requirements for patentability set forth in one or more of 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for double patenting.

**SEVENTH AFFIRMATIVE DEFENSE**  
***(Subject Matter Jurisdiction)***

The Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C § 271(a), (b), and/or (c).

**EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff fails to state a proper claim for an exceptional case under 35 U.S.C. § 285.

**RESERVATION OF ADDITIONAL SEPARATE DEFENSES**

Hetero reserves the right to plead additional separate defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, defenses of unenforceability.

**HETERO USA INC'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT**

Hetero USA Inc. ("Hetero USA" or "Counterclaim-Plaintiff"), by way of counterclaim against Acadia Pharmaceuticals Inc. ("Counterclaim-Defendant"), alleges as follows:

1. Hetero USA is a corporation organized under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.
2. On information and belief, Counterclaim-Defendant is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3611 Valley Centre Drive Suite 300, San Diego, California 92130.
3. As alleged in the Complaint, Counterclaim-Defendant purports to be the owner of U.S. Patent Nos. 7,601,740 ("the '740 patent"), 10,449,185 ("the '185 patent"), and 10,646,480 ("the '480 patent").
4. As alleged in Counterclaim-Defendant's Complaint, Counterclaim-Defendant purports to be the holder of New Drug Application ("NDA") No. 210793.
5. On information and belief, Counterclaim-Defendant caused the '740 patent, the '185 patent and the '480 patent to be listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("The Orange Book") as patents that cover NUPLAZID<sup>®</sup> or its use.
6. Hetero USA submitted Abbreviated New Drug Application ("ANDA") No. 214828 for oral capsules containing pimavanserin tartrate, Eq. 34 mg base ("Hetero USA's ANDA Product") to the Food and Drug Administration ("FDA").

7. Hetero USA's ANDA No. 214828 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '740 patent, '185 patent and the '480 patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Hetero USA's Proposed Product.

8. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and C.F.R. § 314.95(c) on June 25, 2020, Hetero USA sent Counterclaim-Defendant notice of Hetero USA's Paragraph IV certification with ANDA No. 214828 ("Hetero USA's Notice Letter").

9. Hetero USA's Notice Letter contained an offer of confidential access to relevant portions of ANDA No. 214828 to the Counterclaim-Defendant, so that they could determine whether Hetero USA's ANDA Product would infringe any valid claim of the Orange Book-listed patents, pursuant to 21 U.S.C. § 355 (j)(5)(C)(i)(III).

10. Hetero USA's Notice Letter initiated a 45-day statutory period during which Counterclaim-Defendant had the opportunity to file an action for patent infringement.

11. On July 30, 2020, Counterclaim-Defendant filed the instant suit alleging that Hetero USA infringes the '740 patent, the '185 patent and the '480 patent by filing ANDA No. 214828 with the FDA and/or commercially selling, offering for sale, using, and/or manufacturing Hetero USA's ANDA Product.

12. There has been and now is an actual and justiciable controversy between Hetero USA and Counterclaim-Defendant as to whether Hetero USA's ANDA Product infringes, induces infringement, or contributes to the infringement of any valid and enforceable claim of the '740 patent, the '185 patent and the '480 patent.

13. As a consequence of the foregoing, there is an actual and justiciable controversy between Hetero USA and Counterclaim-Defendant as to whether the claims of the '740 patent,

the '185 patent, and the '480 patent have been, are being or will be infringed by filing of ANDA No. 214828 and/or the use, sale, offer for sale, or manufacture of Hetero USA's ANDA Product.

14. As a consequence of the foregoing, there is an actual and justiciable controversy between Hetero USA and the Counterclaim-Defendant as to whether the claims of the '740 patent, the '185 patent, and the '480 patent are valid and enforceable.

15. The filing of this complaint against Hetero USA alleging infringement of the '740 patent, the '185 patent and the '480 patent shows that Counterclaim-Defendant is willing to assert its patents against companies for filing ANDAs referencing NDA No. 214828.

### **JURISDICTION**

16. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

17. This Court has jurisdiction over the subject matter of Hetero USA's counterclaims pursuant to 28 U.S.C. §§ 1331, 1338, 1367, 2201 and 2202.

18. Counterclaim-Defendant, by bringing this action in this district, have consented to and are subject to personal jurisdiction in this district. Hetero USA does not contest personal jurisdiction over it by this Court.

### **FIRST COUNTERCLAIM**

#### **(Declaration of Non-Infringement of U.S. Patent No. 7,601,740)**

19. Hetero USA repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 19 above as if fully set forth herein.

20. Counterclaim-Defendant has asserted the '740 patent against Hetero USA based on the filing of ANDA No. 214828. Counterclaim-Defendant alleges—and Hetero USA denies—that the claims of the '740 patent cover Hetero USA's ANDA Product.

21. The claims of the '740 patent do not, either literally or under the doctrine of equivalents, cover Hetero USA's ANDA Product. Thus, Hetero USA has not infringed and will not infringe the claims of the '740 patent by making, using, selling, offering for sale, marketing or importing Hetero USA's ANDA Product.

22. Hetero USA and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Hetero USA of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Hetero USA, by virtue of filing ANDA No. 214828, neither has nor will in the future infringe any valid and enforceable claim of the '740 patent.

23. Hetero USA is entitled to a judicial declaration that Hetero USA has not infringed and will not infringe any valid and enforceable claim of the '740 patent by virtue of filing ANDA No. 214828 or by making, using, selling, offering for sale, marketing or importing Hetero USA's ANDA Product.

**SECOND COUNTERCLAIM**  
**(Declaration of Invalidity of U.S. Patent No. 7,601,740)**

24. Hetero USA repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 24 above as if fully set forth herein.

25. Counterclaim-Defendant alleges—and Hetero USA denies—that the '740 patent is valid.

26. The claims of the '740 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, and/or for double patenting.

27. Hetero USA and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Hetero USA of sufficient

immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of claims 1-26 of the '740 patent.

28. Hetero USA is entitled to a judicial declaration that claims 1-26 of the '740 patent are invalid.

**THIRD COUNTERCLAIM**  
**(Declaration of Non-Infringement of U.S. Patent No. 10,449,185)**

29. Hetero USA repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 28 above as if fully set forth herein.

30. Counterclaim-Defendant has asserted the '185 patent against Hetero USA based on the filing of ANDA No. 214828. Counterclaim-Defendant alleges—and Hetero USA denies—that the claims of the '185 patent cover Hetero USA's ANDA Product.

31. The claims of the '185 patent do not, either literally or under the doctrine of equivalents, cover Hetero USA's ANDA Product. Thus, Hetero USA has not infringed and will not infringe the claims of the '185 patent by making, using, selling, offering for sale, marketing or importing Hetero USA's ANDA Product.

32. Hetero USA and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Hetero USA of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Hetero USA, by virtue of filing ANDA No. 214828, neither has nor will in the future infringe any valid and enforceable claim of the '185 patent.

33. Hetero USA is entitled to a judicial declaration that Hetero USA has not infringed and will not infringe any valid and enforceable claim of the '185 patent by virtue of filing ANDA No. 214828 or by making, using, selling, offering for sale, marketing or importing Hetero USA's ANDA Product.

**FOURTH COUNTERCLAIM**  
**(Declaration of Invalidity of U.S. Patent No. 10,449,185)**

34. Hetero USA repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 33 above as if fully set forth herein.

35. Counterclaim-Defendant alleges—and Hetero USA denies—that the '185 patent is valid.

36. The claims of the '185 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, and/or for double patenting.

37. Hetero USA and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Hetero USA of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of claims 1-5 of the '185 patent.

38. Hetero USA is entitled to a judicial declaration that claims 1-5 of the '185 patent are invalid.

**FIFTH COUNTERCLAIM**  
**(Declaration of Non-Infringement of U.S. Patent No. 10,646,480)**

39. Hetero USA repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 38 above as if fully set forth herein.

40. Counterclaim-Defendant has asserted the '480 patent against Hetero USA based on the filing of ANDA No. 214828. Counterclaim-Defendant alleges—and Hetero USA denies—that the claims of the '480 patent cover Hetero USA's ANDA Product.

41. The claims of the '480 patent do not, either literally or under the doctrine of equivalents, cover Hetero USA's ANDA Product. Thus, Hetero USA has not infringed and will



not infringe the claims of the '480 patent by making, using, selling, offering for sale, marketing or importing Hetero USA's ANDA Product.

42. Hetero USA and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Hetero USA of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that Hetero USA, by virtue of filing ANDA No. 214828, neither has nor will in the future infringe any valid and enforceable claim of the '480 patent.

43. Hetero USA is entitled to a judicial declaration that Hetero USA has not infringed and will not infringe any valid and enforceable claim of the '480 patent by virtue of filing ANDA No. 214828 or by making, using, selling, offering for sale, marketing or importing Hetero USA's ANDA Product.

**SIXTH COUNTERCLAIM**  
**(Declaration of Invalidity of U.S. Patent No. 10,646,480)**

44. Hetero USA repeats and realleges its responses to the Complaint and the allegations in paragraphs 1 through 43 above as if fully set forth herein.

45. Counterclaim-Defendant alleges—and Hetero USA denies—that the '480 patent is valid.

46. The claims of the '480 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, and/or for double patenting.

47. Hetero USA and Counterclaim-Defendant have adverse legal interests, and there is a substantial controversy between Counterclaim-Defendant and Hetero USA of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of claims 1-20 of the '480 patent.

48. Hetero USA is entitled to a judicial declaration that claims 1-20 of the '480 patent are invalid.

**PRAYER FOR RELIEF**

WHEREFORE Hetero USA respectfully prays for judgment in its favor and against Counterclaim-Defendant, including the following specific relief:

A. Dismissing Counterclaim-Defendant/Plaintiff's Complaint with prejudice and denying each and every request for relief made therein by Counterclaim-Defendant/Plaintiff;

B. Declaring that ANDA No. 214828 has not infringed any valid and enforceable claim of the '740 patent;

C. Declaring that the manufacture, use, sale, offer for sale, or importation of the ANDA Product that is the subject of ANDA No. 214828 has not infringed, does not infringe, and would not infringe any valid and enforceable claim of the '740 patent;

D. Declaring that claims 1-26 of the '740 patent are invalid;

E. Declaring that ANDA No. 214828 has not infringed any valid and enforceable claim of the '185 patent;

F. Declaring that the manufacture, use, sale, offer for sale, or importation of the ANDA Product that is the subject of ANDA No. 214828 has not infringed, does not infringe, and would not infringe any valid and enforceable claim of the '185 patent;

G. Declaring that claims 1-5 of the '185 patent are invalid;

H. Declaring that ANDA No. 214828 has not infringed any valid and enforceable claim of the '480 patent;

I. Declaring that the manufacture, use, sale, offer for sale, or importation of the Proposed Product that is the subject of ANDA No. 214828 has not infringed, does not infringe, and would not, if marketing, infringe any valid and enforceable claim of the '480 patent;

J. Declaring that claims 1-20 of the '480 patent are invalid;

K. Declaring this case exceptional and awarding Hetero USA reasonable attorneys' fees and costs under 35 U.S.C. § 285; and

L. Awarding Hetero USA such other and further relief as the Court may deem just and proper.

Dated: October 5, 2020

Respectfully submitted,

BAYARD, P.A.

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